

Attachment 4

JUL 12 2012

New 510(k) Summary**Alkaline Phosphatase, Amylase and LDH-L Reagents
on the ACE Axcel Clinical Chemistry System****510(k) SUMMARY**

510(k) Owner:	Alfa Wassermann Diagnostic Technologies, LLC 4 Henderson Drive West Caldwell, NJ 07006	
	Contact:	Hyman Katz, Ph.D. Phone: 973-852-0158 Fax: 973-852-0237
Date Summary Prepared:	April 12, 2012	
Device:	Trade Name:	ACE Axcel Clinical Chemistry System
	Classification:	Class 1
	Common/Classification Name:	Analyzer, Chemistry (Photometric, Discrete), For Clinical Use (21 C. F.R. § 862.2610) Product Code JJE
	Trade Name:	ACE Alkaline Phosphatase Reagent
	Classification:	Class 2
	Common/Classification Name:	Nitrophenylphosphate, Alkaline Phosphatase Or Isoenzymes (21 C. F.R. § 862.1050) Product Code CJE
	Trade Name:	ACE Amylase Reagent
	Classification:	Class 2
	Common/Classification Name:	Saccharogenic, Amylase (21 C. F.R. § 862.1070) Product Code CIJ

	<p>Trade Name: ACE LDH-L Reagent</p> <p>Classification: Class 2</p> <p>Common/Classification Name: NAD Reduction/NADH Oxidation, Lactate Dehydrogenase (21 C. F.R. § 862.1440) Product Code CFJ</p>
Predicate Devices:	<p>Manufacturer for analyzer/reagent system predicate:</p> <p><u>Alfa Wassermann ACE Clinical Chemistry System</u> <u>ACE Reagents (K931786)</u></p>
Device Descriptions:	<p>The ACE Axcel Clinical Chemistry System consists of two major components, the chemistry instrument and an integrated Panel PC. The instrument accepts the physical patient samples, performs the appropriate optical or potentiometric measurements on those samples and communicates that data to an integral Panel PC. The Panel PC uses keyboard or touch screen input to manually enter a variety of data, control and accept data from the instrument, manage and maintain system information and generate reports relative to patient status and instrument performance. The Panel PC also allows remote download of patient requisitions and upload of patient results via a standard interface.</p> <p>In the ACE Alkaline Phosphatase Reagent assay, alkaline phosphatase in serum catalyzes the hydrolysis of colorless p-nitrophenyl phosphate to p-nitrophenol and inorganic phosphate. In an alkaline solution (pH 10.5), p-nitrophenol is in the phenoxide form and has a strong absorbance at 408 nm. The rate of increase in absorbance, monitored bichromatically at 408 nm/486 nm, is directly proportional to the alkaline phosphatase activity in the sample.</p> <p>In the ACE AST Reagent assay, α-amylase hydrolyzes the 2-chloro-p-nitrophenyl-α-D-maltotrioxide substrate to release 2-chloro-p-nitrophenol and form 2-chloro-p-nitrophenyl-α-D-maltoside, maltotriose and glucose. The rate of increase in absorbance, monitored bichromatically at 408 nm/ 647 nm, is directly proportional to the α-amylase activity in the sample.</p> <p>In the ACE LDH-L Reagent assay, lactate dehydrogenase catalyzes the conversion of L-lactate to pyruvate. Nicotinamide adenine dinucleotide (NAD^+) acts as an acceptor for the hydrogen ions released from the L-lactate and is converted to reduced nicotinamide adenine dinucleotide (NADH). NADH absorbs strongly at 340 nm whereas NAD^+ does not. Therefore, the rate of conversion of NAD^+ to NADH can be determined</p>

	by monitoring the increase in absorbance bichromatically at 340 nm/647 nm. This rate of conversion from NAD ⁺ to NADH is directly proportional to the lactate dehydrogenase activity in the sample.
Intended Use:	<p>Indications for Use:</p> <p>The ACE Axcel Clinical Chemistry System is an automated, discrete, bench-top, random access analyzer that is intended for <i>in vitro</i> diagnostic use in the quantitative determination of constituents in blood and other fluids.</p> <p>The ACE Alkaline Phosphatase Reagent is intended for the quantitative determination of alkaline phosphatase activity in serum using the ACE Axcel Clinical Chemistry System. Measurements of alkaline phosphatase are used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases. This test is intended for use in clinical laboratories or physician office laboratories. For <i>in vitro</i> diagnostic use only.</p> <p>The ACE Amylase Reagent is intended for the quantitative determination of α-amylase activity in serum using the ACE Axcel Clinical Chemistry System. Amylase measurements are used primarily for the diagnosis and treatment of pancreatitis (inflammation of the pancreas). This test is intended for use in clinical laboratories or physician office laboratories. For <i>in vitro</i> diagnostic use only.</p> <p>The ACE LDH-L Reagent is intended for the quantitative determination of lactate dehydrogenase activity in serum using the ACE Axcel Clinical Chemistry System. Lactate dehydrogenase measurements are used in the diagnosis and treatment of liver diseases such as acute viral hepatitis, cirrhosis, and metastatic carcinoma of the liver, cardiac diseases such as myocardial infarction and tumors of the lung or kidneys. This test is intended for use in physician office laboratories or clinical laboratories. For <i>in vitro</i> diagnostic use only.</p>
Technological Characteristics:	<p>The following is a description of the major features of the ACE Axcel Clinical Chemistry System:</p> <ul style="list-style-type: none"> • System throughput is approximately 160 test results per hour for routine, single reagent chemistries. System throughput will be higher when the test workload includes ISE's. • The instrument has a capacity of 40 reagent containers on board. A reagent cooling system maintains the reagents at 12°C during instrument operation. • Reagent containers are identified by computer coded labels to simplify system operation. All reagents in the system must include an identification label on the container.

	<ul style="list-style-type: none"> • Sample and reagent sensing notify the operator of a depleted condition during operation. • The system performs analysis at a reaction temperature of 37°C. • An electrolyte subsystem capable of measuring sodium, potassium and chloride concentrations is included. • Primary draw tubes may be introduced one at a time into the system for closed tube sampling. Positive tube identification can be achieved with an optional barcode scanner. An aliquot volume sufficient for all tests ordered is transferred and stored and the closed tube is returned to the user. • Sample cups are introduced to the system one at a time or by sample ring segment. • Disposable cuvettes are loaded in bulk and then automatically injected as needed by a cuvette hopper system. The ACE Axccl clinical chemistry optical system is capable of monitoring a maximum of 48 cuvettes at one time. • The absorbance optical system is capable of absorbance measurements in a linear range of 0.0 to 2.0 absorbance units (at 0.67 cm pathlength). Sixteen wavelengths are measured simultaneously using a photodiode array. <p>The ACE Alkaline Phosphatase Reagent is composed of two reagent bottles (Buffer and Substrate Reagent). The reagents contain AMP Buffer (pH 10.45), magnesium acetate, p-nitrophenyl phosphate.</p> <p>The ACE Amylase Reagent is composed of a single reagent bottle. The reagents contain 2-chloro-p-nitrophenyl-α-D-maltotrioxide, sodium chloride, calcium acetate, potassium thiocyanate and MES buffer (pH 6.0).</p> <p>The ACE LDH-L Reagent is composed of two reagent bottles (Substrate and Coenzyme Reagent). The reagents contain L-lactic acid and nicotinamide adenine dinucleotide.</p>
Performance Data:	<p>Performance data for the Alfa Wassermann ACE Reagents run on the Alfa Wassermann ACE Axccl Clinical Chemistry System included precision, accuracy, and detection limit data.</p> <p><u>ACE Alkaline Phosphatase Reagent</u></p> <p><u>Precision:</u> In testing conducted at four alkaline phosphatase levels for 22 days, the within-run CV ranged from 1.3 to 3.2%, and total CV ranged from 2.8 to 4.7%. In precision studies at three separate Physician Office Laboratory (POL) sites over 5 days, the within-run CV ranged from 1.0 to 4.8% and total CV ranged from 2.0 to 5.7%.</p>

Accuracy: In the correlation study, 112 samples with alkaline phosphatase values ranging from 12 to 1363 U/L were assayed on the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x). Least squares regression analysis yielded a correlation coefficient of 0.9997, a standard error estimate of 5.1, a confidence interval slope of 0.978 to 0.987, and a confidence interval intercept of -0.5 to 1.8. In patient correlation studies at three separate POL sites, using the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x), least-squares regression analysis yielded correlation coefficients of 0.9957 to 0.9998, standard error estimates of 6.0 to 25.3, confidence interval slopes of 0.966 to 1.063, and a confidence interval intercepts of -4.0 to 14.5.

Detection limit: The detection limit was 1.3 U/L.

ACE Amylase Reagent

Precision: In testing conducted at four amylase levels for 22 days, the within-run CV ranged from 1.5 to 3.4%, and total CV ranged from 1.7 to 3.6%. In precision studies at three separate Physician Office Laboratory (POL) sites 5 days, the within-run CV ranged from 0.8 to 4.7% and total CV ranged from 0.9 to 5.7%.

Accuracy: In the correlation study, 111 samples with amylase values ranging from 11 to 1650 U/L were assayed on the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x). Least squares regression analysis yielded a correlation coefficient of 0.9997, a standard error estimate of 6.5, a confidence interval slope of 0.953 to 0.962, and a confidence interval intercept of -0.7 to 2.0. In patient correlation studies at three separate POL sites, using the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x), least-squares regression analysis yielded correlation coefficients of 0.9985 to 1.0000, standard error estimates of 3.4 to 22.3, confidence interval slopes of 0.968 to 1.022, and a confidence interval intercepts of -7.7 to 6.7.

Detection limit: The detection limit was 8.5 U/L.

ACE LDH-L Reagent

Precision: In testing conducted at four LDH levels for 22 days, the within-run CV ranged from 1.6 to 3.1%, and total CV ranged from 2.3 to 4.6%. In precision studies at three separate Physician Office Laboratory (POL) sites over 5 days, the within-run CV ranged from 1.1 to 3.0% and total CV ranged from 1.7 to 3.3%.

	<p><u>Accuracy:</u> In the correlation study, 121 samples with LDH values ranging from 22 to 829 U/L were assayed on the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x). Least squares regression analysis yielded a correlation coefficient of 0.9986, a standard error estimate of 7.5, a confidence interval slope of 1.036 to 1.056, and a confidence interval intercept of 2.8 to 7.0. In patient correlation studies at three separate POL sites, using the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x), least-squares regression analysis yielded correlation coefficients of 0.9983 to 0.9993, standard error estimates of 6.3 to 13.1, confidence interval slopes of 0.995 to 1.052, and a confidence interval intercepts of -8.5 to 6.2.</p> <p><u>Detection limit:</u> The detection limit was 8.3 U/L.</p>
Conclusions:	Based on the foregoing data, the device is safe and effective. These data also indicate substantial equivalence to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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Silver Spring, MD 20993

Alfa Wasserman Diagnostic Technologies, LLC
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4 Henderson Drive
West Caldwell, NJ 07006

JUL 12 2012

Re: k113436
Trade Name: ACE Alkaline Phosphatase Reagent
ACE Amylase Reagent
ACE LDH-L Reagent
Regulation Number: 21 CFR §862.1050
Regulation Name: Alkaline phosphatase or isoenzymes test system
Regulatory Class: Class II
Product Codes: CJE, CIJ, CFJ
Dated: June 7, 2012
Received: June 8, 2012

Dear Dr Katz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

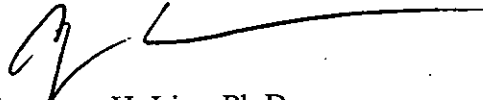
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR); Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>

Sincerely yours,



Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

Device Name: ACE Alkaline Phosphatase Reagent

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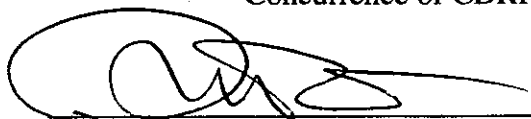
Prescription Use X
(21 CFR Part 801 Subpart D)

AND/OR

Over-The-Counter Use.
(21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K113436